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EXAMINER

AUGHENBAUGH, WALTER

ART UNIT	PAPER NUMBER
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1794

MAIL DATE	DELIVERY MODE
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05/27/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/669,059

Applicant(s)

SCHOENLE ET AL.

Examiner

WALTER B. AUGHENBAUGH

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period **will** apply and **will** expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply **will**, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 74,77-79,84,87,88,130-133,140,142,144-150 and 152 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 74,77-79,84,87,88,130-133,140,142,144-150 and 152 is/are rejected.
- 7) ☒ Claim(s) 149 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

WITHDRAWN REJECTIONS

1. All rejections of the claims under 35 U.S.C. 112, 102 and 103 made of record in the previous Office Action mailed December 2, 2008 have been withdrawn due to Applicant's arguments in the Amendment filed March 2, 2009.

NEW OBJECTIONS

Specification

2. The amendment filed September 11, 2008 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the recitation "the region is attached to a proximal waist of the balloon" of claim 149. See discussion below in 35 U.S.C. 112, first paragraph, rejection of claim 149.

Applicant is required to cancel the new matter in the reply to this Office Action.

3. Claim 149 is objected to because of the following informalities: the term "waist" may cause some confusion/difficulty in interpreting the claim language because the "proximal waist of the balloon" of claim 149 appears to be the same as the "proximal end of the balloon" of claim 74. See paragraph 0089 of the published application and Fig. 3A. However, the fact that different terms are being used suggests that Applicant intends to distinguish between the two. Examiner suggests using the same terminology in claims 74 and 149 regarding the proximal end of the balloon for consistency in claim language, if Applicant intends to refer to the same thing in

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claims claims 74 and 149 with “proximal waist of the balloon” of claim 149 and “proximal end of the balloon” of claim 74. Clarification and/or correction is required.

Appropriate correction is required.

NEW REJECTIONS

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 149 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The recitation “the region is attached to a proximal waist of the balloon” of claim 149 does not appear to be supported in the specification as originally filed.

The phrase “is attached to” indicates that the “region” is a separate component of the catheter: something that can be “attached to” the proximal waist of the balloon. The word “region” normally would indicate that the “region” of X constitutes a portion of X. However, the specification as originally filed does not appear to provide support for the region of the shaft being a separate component of the catheter.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 131, 133 and 149 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 131 recites the limitation "of claim 80" in line 1. There is insufficient antecedent basis for this limitation in the claim. Claim 80 is cancelled.

Claim 133 recites the limitation "of claim 89" in line 1. There is insufficient antecedent basis for this limitation in the claim. Claim 89 is cancelled.

In regard to claim 149, the structure Applicant intends to recite by "the region is attached to a proximal waist of the balloon" cannot be ascertained. The phrase "is attached to" indicates that the "region" is a separate component of the catheter: something that can be "attached to" the proximal waist of the balloon. However, it is unclear whether or not Applicant intends to recite that the "region" is actually a separate component of the catheter. The word "region" normally would indicate that the "region" of X constitutes a portion of X. Clarification and/or correction is required.

Claim Rejections - 35 USC § 103

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

9. Claims 74, 77-79, 84, 87, 88, 130, 132, 140, 142, 144-150 and 152 are rejected under 35 U.S.C. 103(a) as being unpatentable over Callol et al. (USPN 6,709,440).

In regard to independent claim 74, and claims 140 and 150, Callol et al. teach a balloon catheter that corresponds to the balloon catheter as claimed (see, for example, col. 5, lines 27-

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56). Callol et al. teach that the shaft includes a region that comprises a polyamide having a tensile strength of at least 15,000 psi (col. 29, lines 12-30).

Callol et al. fail to explicitly teach that the tensile strength of the polyamide is at least about 21,000 psi, and the recited thickness of the wall of the shaft.

However, since Callol et al. teach that the polyamide of the shaft has a tensile strength of at least 15,000 psi (col. 29, lines 12-30), and that the outer tubular member (which is a component of the shaft, see for example, col. 24, lines 13-31) is formed of a relatively high strength material (col. 29, lines 1-6). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have varied the tensile strength of the polyamide used for the material of the shaft in order to achieve the desired degree of strength of the shaft wall depending on the particular desired end result depending on the desired end use, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art in the absence of unexpected results. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). MPEP 2144.05 II.B.

Furthermore, since Callol et al. teach that the outer tubular member (which is a component of the shaft, see for example, col. 24, lines 13-31) is formed of a relatively high strength material (col. 29, lines 1-6), it would have been obvious to one of ordinary skill in the art at the time the invention was made to have varied the thickness of the wall of the shaft of Callol et al. in order to achieve the desired degree of strength of the shaft wall depending on the particular desired end result depending on the desired end use, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art

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in the absence of unexpected results. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).
MPEP 2144.05 II.B.

In regard to claim 77, Callol et al. teach the catheter as discusse above. Callol et al. teach that the tubular members may comprise one or more layers (col. 23, line 66-col. 24, line 13). While Callol et al. do not specifically teach that the different layers have different flexibilities, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used different materials for the different layers in order to achieve the optimal combination of properties obtainable from the different materials of the different layers. Different materials have different flexibilities, so the layers that would result from the catheter having a multilayered shaft having different materials would have different flexibilities.

In regard to claim 78, Callol et al. teach the catheter as discusse above.

Callol et al. fail to explicitly teach that the tensile strength of the polyamide is at least about 22,500.

However, since Callol et al. teach that the polyamide of the shaft has a tensile strength of at least 15,000 psi (col. 29, lines 12-30), and that the outer tubular member (which is a component of the shaft, see for example, col. 24, lines 13-31) is formed of a relatively high strength material (col. 29, lines 1-6). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have varied the tensile strength of the polyamide used for the material of the shaft in order to achieve the desired degree of strength of the shaft wall depending on the particular desired end result depending on the desired end use, since it has been held that discovering an optimum value of a result effective variable involves

only routine skill in the art in the absence of unexpected results. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). MPEP 2144.05 II.B.

In regard to claim 130, Callol et al. teach that a polyamide copolymer is a suitable polyamide for the material of the shaft (col. 29, lines 16-24). While Callol et al. fail to explicitly teach that the tensile strength of the polyamide copolymer is at least about 21,000, Callol et al. teach that the polyamide of the shaft has a tensile strength of at least 15,000 psi (col. 29, lines 12-30), and that the outer tubular member (which is a component of the shaft, see for example, col. 24, lines 13-31) is formed of a relatively high strength material (col. 29, lines 1-6). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have varied the tensile strength of the polyamide copolymer used for the material of the shaft in order to achieve the desired degree of strength of the shaft wall depending on the particular desired end result depending on the desired end use, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art in the absence of unexpected results. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). MPEP 2144.05 II.B.

In regard to claims 144-149, the structural limitations that are positively recited in claims 144-149 fall within the scope of the teachings of Callol et al. Limitations such as “the distal inner lumen is a guide wire lumen” (claim 145) are intended use phrases that have not been given patentable weight, since it has been held that a recitation with respect to the manner in which a claimed article is intended to be employed does not differentiate the claimed article from a prior art article satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQd 1647 (1987).

In regard to independent claim 84, and claims 142 and 152, Callol et al. teach a balloon catheter that corresponds to the balloon catheter as claimed (see, for example, col. 5, lines 27-56). Callol et al. teach that the shaft includes a region that comprises a polyamide having a tensile strength of at least 15,000 psi (col. 29, lines 12-30).

Callol et al. fail to explicitly teach that the hoop stress of the polyamide is at least about 3300 psi, and the recited thickness of the wall of the shaft.

However, Callol et al. teach that the polyamide of the shaft has a tensile strength of at least 15,000 psi (col. 29, lines 12-30), and that the outer tubular member (which is a component of the shaft, see for example, col. 24, lines 13-31) is formed of a relatively high strength material (col. 29, lines 1-6). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have selected a polyamide having a certain hoop stress in order to achieve the desired degree of strength of the shaft wall depending on the particular desired end result depending on the desired end use, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art in the absence of unexpected results. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). MPEP 2144.05 II.B.

Furthermore, since Callol et al. teach that the outer tubular member (which is a component of the shaft, see for example, col. 24, lines 13-31) is formed of a relatively high strength material (col. 29, lines 1-6), it would have been obvious to one of ordinary skill in the art at the time the invention was made to have varied the thickness of the wall of the shaft of Callol et al. in order to achieve the desired degree of strength of the shaft wall depending on the particular desired end result depending on the desired end use, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art

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in the absence of unexpected results. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). MPEP 2144.05 II.B.

In regard to claim 87, Callol et al. teach the catheter as discusse above. Callol et al. teach that the tubular members may comprise one or more layers (col. 23, line 66-col. 24, line 13). While Callol et al. do not specifically teach that the different layers have different flexibilities, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used different materials for the different layers in order to achieve the optimal combination of properties obtainable from the different materials of the different layers. Different materials have different flexibilities, so the layers that would result from the catheter having a multilayered shaft having different materials would have different flexibilities.

In regard to claim 78, Callol et al. teach the catheter as discusse above.

Callol et al. fail to explicitly teach that the hoop stress of the polyamide is at least about 3500.

However, Callol et al. teach that the polyamide of the shaft has a tensile strength of at least 15,000 psi (col. 29, lines 12-30), and that the outer tubular member (which is a component of the shaft, see for example, col. 24, lines 13-31) is formed of a relatively high strength material (col. 29, lines 1-6). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have selected a polyamide having a certain hoop stress in order to achieve the desired degree of strength of the shaft wall depending on the particular desired end result depending on the desired end use, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art in the absence of unexpected results. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). MPEP 2144.05 II.B.

In regard to claim 132, Callol et al. teach that a polyamide copolymer is a suitable polyamide for the material of the shaft (col. 29, lines 16-24). While Callol et al. fail to explicitly teach that the hoop stress of the polyamide copolymer is at least about 3300, Callol et al. teach that the polyamide of the shaft has a tensile strength of at least 15,000 psi (col. 29, lines 12-30), and that the outer tubular member (which is a component of the shaft, see for example, col. 24, lines 13-31) is formed of a relatively high strength material (col. 29, lines 1-6). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have selected a polyamide copolymer having a certain hoop stress in order to achieve the desired degree of strength of the shaft wall depending on the particular desired end result depending on the desired end use, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art in the absence of unexpected results. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). MPEP 2144.05 II.B.

Response to Arguments

10. Applicant's arguments regarding the 35 U.S.C. 112, 102 and 103 rejections of claims are moot due to the withdrawal of these rejections due to Applicant's arguments in the Amendment filed March 2, 2009.

Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Walter B. Aughenbaugh whose telephone number is (571) 272-1488. While the examiner sets his work schedule under the Increased Flexitime Policy, he can normally be reached on Monday-Friday from 8:45am to 5:15pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rena Dye, can be reached on (571) 272-3186. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Walter B Aughenbaugh /

Examiner, Art Unit 1794

5/26/09